DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 29, 2015

Wright Medical Technology, Incorporated
Mr. Val Myles
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K150252
Trade/Device Name: PHALINX Hammertoe System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 29, 2015
Received: February 3, 2015

Dear Mr. Val Myles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150252

Device Name
PHALINX® Hammertoe System

Indications for Use *(Describe)*
The PHALINX® Hammertoe System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Cannulated Implants in the PHALINX® Hammertoe Fixation System can be used with k-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the WMT PHALINX® Hammertoe System.

(a)(1). Submitted By:

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Date: January 29, 2015

Contact Person:

Val Myles
Regulatory Affairs Specialist
Office - (901) 290-5162
Fax – (901) 867-4190

(a)(2). Proprietary Name: PHALINX® Hammertoe System

Common Name: Smooth or threaded metallic bone fixation fastener

Classification Name and Reference: 21 CFR 888.3040 – Class II

Device Product Code, Device Panel: HWC – Orthopedic

(a)(3). Predicate Device:

K142585: PHALINX® Hammertoe System
K140148: PRO-TOE® Hammertoe Fixation System
K132895: WMT Implantable K-Wires

(a)(4). Device Description

The PHALINX® Hammertoe System implants are a single piece titanium device offered in straight cannulated and 10° solid options. The implants have proximal and distal fixation features and are offered in multiple sizes. This submission seeks to add PHALINX® K-Wires to the system for use with cannulated implants. The PHALINX® K-wires are offered in surgical grade stainless steel. A range of diameters and lengths are offered from the manufacturer and planning should be conducted prior to implantation to determine the best fit.

(a)(5). INTENDED USE

The PHALINX® Hammertoe System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Cannulated Implants in the PHALINX® Hammertoe System can be used with k-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

(a)(6). Technological Characteristics Comparison

The subject PHALINX® Hammertoe System design is identical to the currently marketed PHALINX® Hammertoe System.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Testing related to bending and pull-out strength was previously provided in the predicate device filings. Therefore, no testing was provided for the subject device as the design is identical.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate device.